SPOOR AND FISHER

Express Mail Cert. No.: EV 316 332 220 US
Inventor: Michael Christian Norris
Application No.: 10/505,291
Attorney Docket No.: 45669-304008

REPUBLIC OF SOUTH AFRICA
REVENUE FORM P.1.

REVENUE STAMPS OR REVENUE FRANKING MACHINE IMPRESSION "R" 30.00

INKOMSTE
REPUBLIEK VAN SUID AFRIKA
HR 70
OFFICIAL DATE STAMP

"R" 10.00 INKOMSTE SUID AFRIKA HR 70

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978

APPLICATION FOR A PATENT
AND ACKNOWLEDGEMENT OF RECEIPT
(Section 30 (1) – Regulation 22)

The grant of a patent is hereby requested by the undermentioned applicant on the basis of the present application filed in duplicate

	OFFICIAL APPLICATION No.	S & F REFERENCE
21 01	845785	JP/A 497

NAAM VERANDER 27-2-96 Adcock Ingram Pharmaceuticals Limited.

	FULL NAME(S) OF APPLICANT(S)
71	NAME CHANGED ADCOCK-INGRAM ~~LABORATORIES~~ PHARMACEUTICALS LIMITED NAAM VERANDER 9-1-91 NAME CHANGED

ADDRESS(ES) OF APPLICANT(S)

105 QUARTZ STREET, HILLBROW

TITLE OF INVENTION

54 PHARMACEUTICAL UNIT

PRIORITY IS CLAIMED AS SET OUT ON THE ACCOMPANYING FORM P.2.

~~THIS APPLICATION IS FOR A PATENT OF ADDITION TO PATENT APPLICATION NO.~~

21 01

~~THIS APPLICATION IS A FRESH APPLICATION IN TERMS OF SECTION 37 AND BASED ON APPLICATION NO.~~

21 01

THIS APPLICATION IS ACCOMPANIED BY:

- [x] 1. ~~A provisional specification~~ or two copies of a complete specification of .....7..... pages.
- [ ] 2. Drawings of ..... sheets
- [x] 3. Publication particulars and abstract (Form P.8. in duplicate)
- [ ] 4. A copy of Figure ..... of the drawings (if any) for the abstract
- [x] 5. Assignment of invention
- [ ] 6. Certified priority document(s) (State number)
- [ ] 7. Translation of the priority document(s)
- [ ] 8. An assignment of priority rights
- [x] 9. A copy of the Form P.2. and the specification of S.A. Patent Application No 21 01 83/4272
- [x] 10. A declaration and power of attorney on Form P.3.
- [ ] 11. Request for ante-dating on Form P.4.
- [ ] 12. Request for classification on Form P.9.
- [x] 13. Form P.2 in duplicate

74 ADDRESS FOR SERVICE: SPOOR AND FISHER, SANDTON, ~~PRETORIA~~, JOHANNESBURG

REGISTRAR OF DESIGNS, TRADE MARKS AND COPYRIGHT
RECEIVED
26 -07- 1984
OFFICIAL DATE STAMP
PRETORIA MODELLE,

Dated this 26th Day of JULY 1984

AM Dyer

SPOOR AND FISHER
APPLICANTS PATENT ATTORNEYS

REGISTRAR OF PATENTS

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FORM P.7
(To be lodged in duplicate)

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978

COMPLETE SPECIFICATION

(Section 30(1) – Regulation 28)

OFFICIAL APPLICATION NO.

21	01	845735

LODGING DATE

22	26 JULY 1984

INTERNATIONAL CLASSIFICATION

51	A 61 K

FULL NAME(S) OF APPLICANT(S)

71	ADCOCK-INGRAM ~~LABORATORIES~~ PHARMACEUTICALS LIMITED NAAM VERANDER NAME CHANGED 9-1-91

~~NAAM VERANDER~~ 27-2-91
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FULL NAME(S) OF INVENTOR(S)

72	BINIOMIN KRENGEL

TITLE OF INVENTION

54	PHARMACEUTICAL UNIT

BACKGROUND OF THE INVENTION

This invention relates to pharmaceutical units.

There are many anti-inflammatory compounds presently on the market. Among these compounds may be mentioned indomethacin, flubiprofen, ketoprofen, ibuprofen, fenoprofen, indoprofen, fenbufen and naproxen. These compounds are used primarily for their anti-inflammatory properties, although some of them do exhibit other useful therapeutic indications.

The literature contains reports on clinical studies involving administering ibuprofen or flubiprofen with paracetamol or aspirin as a supplemental analgesic.

SUMMARY OF THE INVENTION

According to the invention, there is provided a dose comprising at least one pharmaceutical unit, the or each unit containing a combination of ibuprofen and at least one analgesic agent as active ingredients, the dose providing a therapeutically effective amount of each active ingredient. Generally, the dose will comprise at least two units.

It is an essential aspect of the invention that each dose, that is the amount which is administered to a warm-blooded animal such as a human at any given time, provides a therapeutically effective amount of both active ingredie. Thus, the dose will produce both anti-inflammatory and analgesic effects in the animal to which it is administered.

The units will generally be in orally administrable form and will typically be in the form of tablets, capsules or a quantity of liquid.

DETAILED DESCRIPTION OF THE INVENTION

Where a single analgesic agent is used in the units, that agent is preferably paracetamol. Where more than one analgesic agent is used in the units, the agents are preferably paracetamol and codeine. The codeine, when used, may be used in the form of the base or a pharmaceutically-acceptable salt, e.g. the phosphate or sulphate salt. The paracetamol, when used, provides the composition with anti-pyretic properties as well.

Several doses will generally be administered per day so as to provide a warm-blooded animal with 800 to 2000mg of ibuprofen and 1000 to 2500mg of analgesic per day. Thus, for example, the units may be provided in

the form of tablets each containing 200mg of ibuprofen and 250mg of paracetamol. Two tablets may be taken four times daily to provide the desired daily dose of ibuprofen and paracetamol.

Examples of the invention will now be described.

EXAMPLE 1

Tablets containing ibuprofen as anti-inflammatory agent and paracetamol and codeine as analgesic agents were produced. Each tablet contained the ingredients set out below:

Ingredient	Quantity per Tablet
Paracetamol	250 - 300 mg
Ibuprofen	170 - 230 mg
Codeine	5 - 30 mg
Binders	5 - 30 % of core weight
Diluents	5 - 30 % of core weight
Disintegrant	0,5 - 10 % of core weight
Lubricant	0,5 - 2 % of core weight
Core Weight	460 - 760 mg

The tablet cores were formulated by conventional procedures, and then each tablet core was coated with a sugar coating, colouring agents, a binder, a lacquer and polishing aids. Alternatively, a conventional solvent or water-based film coat may be applied to the tablet core.

These tablets are suitable for the treatment of injury caused by excessive prostaglandin activity by oral administration of at least two tablets four times a day.

EXAMPLE 2

Capsules containing ibuprofen as anti-inflammatory agent, and paracetamol and codeine as analgesic agents were produced. Each capsule contained the ingredients set out below:

Ingredient	Quantity per Capsule
Paracetamol	250 - 300 mg
Ibuprofen	170 - 230 mg
Codeine	5 - 30 mg
Binder/Diluents	0,1 - 15 % by weight of the total ingredients
Lubricant	0,1 - 2 % by weight of the total ingredients

The ingredients were mixed together by conventional procedures, and the mixture was then filled into Size 0 capsules.

The capsules are suitable for the treatment of injury caused by excessive prostaglandin activity by oral administration of at least two capsules four times a day.

EXAMPLE 3

A liquid containing ibuprofen as anti-inflammatory agent, and paracetamol and codeine as analgesic agents was produced. Each 30ml dose of the liquid contained the following ingredients:

Ingredient	Quantity per 30ml of the Liquid
Paracetamol	250 - 300 mg
Ibuprofen	170 - 230 mg
Codeine	5 - 30 mg
Solubilisers/Stabilisers	15 - 40 % by weight of 30ml of the liquid
Colouring Agents	0,2 - 2 % by weight of 30ml of the liquid
Alcohol	4 - 18 % by weight of 30ml of the liquid
Preservative	0,1 - 1 % by weight of 30ml of the liquid

The liquid was formulated by conventional procedures.

The liquid is suitable for the treatment of injury caused by excessive prostaglandin activity by oral administration of at least two tablespoons (30ml) four times a day.

CLAIMS

1.
A dose comprising at least one pharmaceutical unit, the or each unit containing a combination of ibuprofen and at least one analgesic agent as active ingredients, the dose providing a therapeutically effective amount of each active ingredient.

2.
A dose according to claim 1 comprising at least two units.

3.
A dose of claim 1 or claim 2 wherein the analgesic agent is paracetamol.

4.
A dose of claim 1 or claim 2 wherein a combination of analgesic agents is used, that combination being paracetamol and codeine.

5.
A dose of any one of claims 1 to 4 the or each unit is a tablet, a capsule or a quantity of liquid.

6.
A composition of claim 1 substantially as herein described with reference to any one of the Examples.

DATED this 26th day of JULY 1984

.....A.M.Dyer.....
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